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Signed K Behen

Dated 21 April 2009

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19 FEB 2001

The Patent Office
Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference — P71654GB

2. Patent application number *(The Patent Office will fill in this part)* — 0103893.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Niagara Manufacturing Limited
Colomendy Industrial Estate
Rhyl Road
Denbigh
Denbighshire
North Wales
LL16 5TS

Patents ADP number *(if you know it)* 00625939001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — Leg Ulcer or Wound Vibratory Treatment and Device

5. Name of your agent *(if you have one)*

Harrison Goddard Foote

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Fountain Precinct
Leopold Street
Sheffield
S1 2QD

Patents ADP number *(if you know it)* 7914237001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

yes

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Continuation sheets of this form	
Description	13
Claim(s)	4
Abstract	1
Drawing(s)	13

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 16 February 2001

12. Name and daytime telephone number of person to contact in the United Kingdom Mark G F Lunt 0114 2747301

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a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.*

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d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

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Leg Ulcer or Wound Vibratory Treatment and Device

The present invention relates to a vibratory massage device for the treatment of open sore ulcers or other wounds on a human or animal body, and a method of treatment of open sore ulcers or other wounds on a human or animal body.

It is well understood that three-dimensional vibration (referred to as cycloidal vibration) has beneficial effects in improving blood circulation, joint mobility, and respiratory conditions, and relieving tension. Such vibration is in the frequency range of 15 to 75 Hz with an amplitude varying between 0.1 and 0.5 mm, depending on the orthogonal direction.

Decubitus ulcers are caused by continuous pressure at specific points of the body when a patient is immobile for extended periods of time. It is known that vibration can assist in preventing the development of such sores and US-A-5606754 suggests a bed which has vibration means to reduce the incidence of bed sores.

Venous ulcers are caused by cracks in dry skin and are notoriously difficult to heal, particularly in elderly patients. The current method of treatment is to cover the affected skin area with a dressing, in order to keep the skin moist and prevent infection from entering the sore, and to immobilise the sore in order to facilitate healing. However, some patients suffer from venous ulcers for extended periods of time in the order of months or even

years before they heal, if ever. There is an evident need for more efficient treatment of ulcers.

US-A-5948009 discloses an ablation electrode for treating canker sore in which vibratory massage is applied to create a lesion. This is said to create the conditions for subsequent healing.

It is an object of the present invention to provide an improved method of treatment of ulcers and wounds.

In accordance with a first aspect of the present invention there is provided a method of treatment of ulcers and wounds of the human or animal body, which method comprises the step of subjecting the body in the area of the ulcer or wound to mechanical vibrations for an effective period of time, said vibrations having a frequency of between 15 and 75 Hz, and an amplitude of between 0.1 and 0.5 mm.

Preferably, said vibrations have components in three orthogonal directions, said frequency being the same or different in each direction, and said amplitude being the same or different in each direction. Preferably said period is more than fifteen minutes, ideally about thirty minutes. The treatment is preferably repeated three times a day.

In another aspect, the present invention provides an ulcer or open wound treatment device comprising:

a drive unit adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each orthogonal direction of

between 0.1 and 0.5 mm;

a pad connected to said drive unit; and

pressure applying means by which the pad may be pressed against the limb of the animal or human.

Preferably, said pressure applying means comprises a strap by means of which the pad may be secured to said limb.

Preferably, the drive unit is substantially cylindrical. It may have a casing mounting a motor having an armature parallel the axis of the cylinder. The motor may drive an eccentrically mounted weight to provide oscillations of the casing in a radial plane. The motor may be mounted through flexible mountings in the casing so that a component of the vibration is created in an axial direction of the armature.

GB-A-2096899 describes a conventional analogue control of a universal AC motor for a vibration device, which control is found not to provide a smooth delivery of power to the motor so that, at some frequencies, the three-dimensional nature of the vibrations is lost.

Preferably, therefore, the motor is electrically powered from mains AC electricity, the drive unit including digital control means to ensure smooth supply of energy to the motor.

Said digital control means preferably comprises:

a detector for each zero crossing point of the AC power supply and adapted to disconnect power from the motor when said crossing point is detected;

a timer comprising a counter started by said detector;

a comparator to compare the count of said counter with a number stored in a memory and to switch power to the motor when said count equals said number.

Preferably, a low voltage transformer is disposed between the power supply and detector. A rectifier may convert the power supply to the motor to DC, if the motor is a DC motor.

Preferably said number is adjustable to vary the power supplied to the motor, and hence its speed of rotation and hence said frequency.

Preferably said counter is capable of providing about 250 counts in each half cycle of the power supply.

Preferably the drive unit operates at a frequency of between 30 and 60 Hz.

When the method above employs the device provided by the present invention, the device may be applied to the leg of a patient suffering venous ulcers by said pressure applying means and so that, in use, the device delivers vibrations in the leg of the patient at a frequency of between 20 and 50 Hz, and with an RMS acceleration in the axial direction of the tibial bone of between 5 and 15 ms^{-2}, and in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2}.

Preferably, the device delivers vibrations in the leg of the patient at a frequency of about 30 Hz, and with an RMS acceleration in the axial direction of the tibial bone of about 10 ms^{-2}, and in a radial plane with respect to

the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2}.

Despite the apparent contrary indication that movement will unsettle the healing of wounds, and particularly venous ulcers, it has been surprisingly discovered that cycloid vibrations, have a beneficial effect on their healing. Without being reliant on any particular theory, this beneficial effect may be due to improved blood circulation caused by the vibrations and increased moisture in the upper dermis and epidermis. Indeed, the healing effects of the present invention are especially felt when two optional features of the invention are fully exploited. The first is the three-dimensional aspects of the vibration; some benefit is experienced with two-dimensional vibration but significantly enhanced effects have been noted with three-dimensional vibrations, particularly when employing the motor control described above which provides smooth power delivery to the motor. The second is the pressure applying means, which serves to unite the patient's limb with the device and ensures deep transmission of the vibrations into the flesh of the patient.

The invention is further described hereinafter, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 is a perspective view of a vibratory massage device in accordance with the present invention, (having attached thereto a transducer pack analysing the vibrations of the pad in three orthogonal directions x, y and z);

Figure 2 is an assembly drawing of a drive unit and

frame of the device of Figure 1;

Figure 3 is a side view of the device of Figure 1 strapped to a patient's leg with the drive unit at the heel of the patient;

Figure 4 is a similar view to Figure 3, but with the drive unit under the knee of the patient;

Figure 5 is a perspective view of the device of Figure 1, with the casing open;

Figure 6 is a top view of the drive unit with the casing open;

Figure 7 is a schematic representation of the control function of the motor of the drive unit;

Figures 8 a to j are graphs of RMS acceleration of the vibrations produced under varying conditions in the three orthogonal directions x, y and z, as well as the frequency of the vibrations;

Figures 9a and b are respectively graphs of acceleration in each direction plotted against time, and a frequency range plot in each direction, both at a preferred speed of operation;

Figures 10a and b are as Figure 9, but at a higher speed; and,

Figures 11a, b and c show the frequency of operation for different conditions of operation against speed setting of the device.

In the drawings, a vibratory massage device 10 in accordance with the present invention comprises a drive unit 12. The drive unit comprises a casing 14 housing an electric low voltage DC motor 16 mounted in the casing through flexible mountings 18,20. The motor drives an eccentric weight 22 mounted on a fan 23 on each end of an

armature 24. On rotation of the armature 24 motor 16 imparts a vibration in the casing 14 in a radial plane (x,y) with respect to the armature 24. Because the mountings 18,20 are soft, a component of the vibration occurs in a direction orthogonal (z) to the radial plane. Consequently, the vibration of the casing in response to the vibration of the motor is three-dimensional.

To the casing is fixed, by screws 29 (see Figure 6) retained in apertures 25 of the casing, a frame 27. On the frame is disposed fabric cushioning to form a pad 110. The cushioning covers the drive unit 12 with a sleeve 40.

The motor is adapted to rotate at about 2400 rpm providing a frequency of vibration of about 40 Hz. Depending on various factors (primarily connected with the degree of restraint placed upon the device by its location on the limb of an animal). the amplitude of vibration in each direction may be different and between about 0.1 mm and 0.5 mm.

However, a speed control arrangement 90 is provided (see Figure 7), conveniently disposed in a separate hand unit (not shown). Arrangement 90 controls the power supplied to the motor, and is connected to AC mains voltage 92, which typically is between 50-60 Hz. The mains supply is connected to a double bobbin isolation transformer T having a nominal 24volt AC output. That supply is fed to a switch/rectifier 94, which in turn provides power to the motor 16 along cable 32.

However, a detector 96 detects the output of the transformer T and activates the switch 94 to commence

supply of current to the motor 16 when the voltage is zero; that is to say, at each zero crossing of the supply voltage.

At the same time, the detector 96 activates a timer 98 to commence counting, the output of which counter is supplied to a comparator 100. The comparator 100 is also supplied with the value of a number stored in a memory 102 and, when the count of the counter 98 reaches the number stored in the memory 102, the comparator activates the switch 94 to interrupt supply of current to the motor 16.

The memory is provided with means 104 by which the number stored can be changed, so that the speed of the motor can be varied. Conveniently, it is found that the counter should count at a rate of about 25 KHz giving about 250 steps in each half cycle.

Because the frame 27 is rigidly fixed to the casing 14 of the drive unit 12, vibrations of the drive unit 12 are therefore transmitted to the pad 110. The pad is about 400 mm long and about 250 mm wide at the motor end and about 200 mm wide at its other end.

In use, a patient suffering from a leg ulcer lays the affected leg 29 longitudinally along the pad. Whether the motor is at the heel end 31 of the leg, as shown in Figure 3, or is under the knee 33, as shown in Figure 4, is a matter of patient choice. However, if an ulcer is on the patient's ankle or lower leg, the former arrangement may be preferable, whereas if it is on the calf or higher, the latter arrangement may provide more direct delivery of vibrations to the site and environment of the ulcer.

Pressure applying means in the form of a strap 46 is employed to press the leg into close contact with the pad 110, although any means will do, such as a weight. The strap 46 conveniently is separate from the pad and comprises a band of material having hooped nylon on one surface and hooked nylon on the other. When its ends are overlapped and pressed together after wrapping around the patient's leg and pad, the strap secures the pad to the patient's leg. The strap is about 100 mm wide.

In any event, Table 1 shows the results of preliminary trials conducted on patients suffering long term problems with ulcers. In each case, the patient arranged a device 10 in accordance with the present invention as shown in Figures 3 or 4 with a strap 46 comfortably, but firmly, pressing the pad 110 against the patient's leg.

The motor control was switched to setting 5 and vibration was effected for about thirty minutes 3 times per day. The results of these treatments are shown in Table I below.

In each case the conventional treatment regime was maintained, along side the vibration treatment. This comprised keeping wounds dressed with two-layer pressure bandages to reduce the potential for infection. Dressings were changed bi-weekly, unless no suppuration or weeping was evident, in which case only weekly change of dressings were effected.

Patient Age and Sex	Age of Ulcer Weeks	Position of Ulcer	Vibration treatment (Weeks)	Reduced Swelling Y/N	Pain * Reduction Start/End	Improved Mobility Y/N	Condition of Ulcer after treatment
84M	100	Ankle	9	Y **	0/0		Reduced Size
84F	6	Above ankle	6	Y	2/0.5 (no pain at nights		Scab in 3 weeks, healed in 6 weeks
73M	17	Ankle	10	Y	2/less		60% healed
85F	39	Above ankle	10	N	5/1		Reducing slowly
86F	17	Above ankle	5	Y	1/0 @ week 4		HEALED
73M	17	Small ulcers	5	N	1/0 @ week 2		HEALED
54M	75	Ankle	2	Y (after 4 days)	0/0		Improvement after 4 days
73M	200	Ankle	2	Y	2.5/1.5		Improving
90M	50	Ankle	2	Minimal	3.5/2.5		Healing

Table I

* Pain is on scale 0 to 5 where 0 is no pain and 5 is intense pain

** Temporary increase in swelling at week 5 but reduced overall

As can be seen from Table I above, the response of patients, even those afflicted with long term ulcers that had hitherto failed to respond to conventional methods of treatment, was in all cases favourable with healing to a greater or lesser extent being effected in each case.

Turning now to Figures 8 to 11, these illustrate graphically the vibration regime established by the pad under the conditions shown in Table II below.

Condition	Subject	Motor at	Support	Strap	Measured at
1	A	Knee	Free	Tight	Middle
2	A	Knee	Firm	Tight	Middle
2A	A	Knee	Soft	Tight	Middle
3	A	Knee	Soft	Tight	Motor end
4	A	Knee	Soft	Loose	Middle
5	A	Heel	Soft	Tight	Middle
6	A	Heel	Soft	Tight	Other end
7	A	Heel	Firm	Tight	Middle
8	B	Heel	Firm	Tight	Middle
9	B	Heel	Soft	Tight	Middle

Table II

The same subject person (A) was used in most tests. The position of the motor was varied between under the "Knee" (Figure 4 arrangement) or at the "Heel" (Figure 3

arrangement). The leg with the pad attached was either "Free" (not shown), supported on a "Firm" base, or supported on a "Soft" cushion 37. The strap 46 was either "Tight" or, in one case, "Loose". Measurements of accelerations were made using accelerometer transducers positioned to measure in each of the three axes x, y and z. The transducers (not shown) were disposed on a base 35 (see Figure 1) between the pad 110 and the subject's leg 29. The base was either in the "Middle" of the pad, at the "Motor end" thereof, or it's "Other end". The use of quotation marks is merely a reference to the same terms used in Table II above.

Referring first to Figures 11a, b and c, in most conditions, the frequency of operation was consistently proportional to speed setting. However, when a particularly rigid connection is achieved (see conditions 7 and 8 where the motor was under the heel of the subject, there was firm support, and a tight strap), the subject's leg will have absorbed substantial energy from the device. This results in a reduction in the increase of speed and frequency with increasing speed setting.

Referring to Figures 8a to j, it can be seen that, with increasing speed, the acceleration in the x direction, which is in the longitudinal direction with respect to the subjects leg, increases exponentially. On the other hand, in the y and z directions, the increase is more proportional and in some cases not especially apparent. It is suspected that for this reason is it found in practice that speed setting 5 appears to be the optimal treatment speed. Indeed, in some conditions, the z component of

acceleration almost disappears at higher speeds, leaving essentially just one dimension (x) to the vibration, with a minor component in the y direction.

However, at speed setting 5 or thereabouts, the vibration is quite evenly three dimensional.

In Figures 9a, the actual acceleration in each direction is plotted against time so that, for example, over about 0.1 seconds 2.5 acceleration cycles occur. This equates to a frequency of about 25 Hz, the amplitude of the accelerations being greatest in the x direction and least in the z direction. In Figure 9, the speed setting is 4.5, whereas in Figure 10 it is 9.5, so that about six acceleration cycles of substantially greater amplitute occur in the measurement period. This equates with a frequency of about 60 Hz.

In both Figures 9b and 10b, the frequency range is plotted against the acceleration at each frequency and it can be seen that there is only one spike of any significance in each direction at both speed levels.

CLAIMS

1. An ulcer or open wound treatment device comprising:

a drive unit adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each orthogonal direction of between 0.1 and 0.5 mm;

a pad connected to said drive unit; and

pressure applying means by which the pad may be pressed against the limb of the animal or human.

2. A device as claimed in claim 1, in which said pressure applying means comprises a strap by means of which the pad may be secured to said limb.

3. A device as claimed in claim 1 or 2, in which said drive unit is substantially cylindrical.

4. A device as claimed in claim 3, in which the drive unit comprises a casing mounting a motor having an armature parallel the axis of the cylinder.

5. A device as claimed in claim 4, in which said motor drives an eccentrically mounted weight to provide oscillations of the casing in a radial plane.

6. A device as claimed in claim 5, in which said motor is mounted through flexible mountings in the casing so that a component of the radial oscillations is created in an axial direction of the armature.

7. A device as claimed in claim 4, 5 or 6, in which the motor is electrically powered from mains AC electricity, the drive unit including digital control means to ensure smooth supply of energy to the motor.

8. A device as claimed in claim 7, in which said digital control means comprises:

a detector for each zero crossing point of the AC power supply and adapted to disconnect power from the motor when said crossing point is detected;

a timer comprising a counter started by said detector;

a comparator to compare the count of said counter with a number stored in a memory and to switch power to the motor when said count equals said number.

9. A device as claimed in claim 8, in which a low voltage transformer is disposed between the power supply and detector.

10. A device as claimed in claim 9, in which a rectifier converts the power supply to the motor to DC and the motor is a DC motor.

11. A device as claimed in claim 8, 9 or 10, in which said number is adjustable to vary the power supplied to the motor, and hence its speed of rotation and hence said frequency.

12. A device as claimed in any of claims 8 to 11, in which said counter is capable of providing about 250 counts in each half cycle of the power supply.

13. A device as claimed in any preceding claim, in which said pad comprises a frame rigidly fixed to the drive unit to transmit vibrations into the pad.

14. A device as claimed in any preceding claim, in which said pad is elongate, of length between 300 and 500 mm and width between 100 and 200 mm, said drive unit being mounted at one end of said pad.

15. A device as claimed in claim 14, in which the pad tapers from the end at which the drive unit is disposed.

16. A device as claimed in claim 14 or 15, when dependent on claim 2, in which the strap is disposed about half way along the length of the pad.

17. A device as claimed in any preceding claim, in which the drive unit operates at a frequency of between 30 and 60 Hz.

18. A method of treatment of ulcers and wounds of the human or animal body, which method comprises the step of subjecting the body in the area of the ulcer or wound to mechanical vibrations for an effective period of time, said vibrations having a frequency of between 15 and 75 Hz, and an amplitude of between 0.1 and 0.5 mm.

19. The method of claim 18, in which said vibrations have components in three orthogonal directions, said frequency being the same or different in each direction, and said amplitude being the same or different in each direction.

20. The method of claim 18 or 19, in which said period is more than fifteen minutes, ideally about thirty minutes.

21. The method of claim 18, 19 or 20, in which the treatment is repeated three times a day.

22. The method of any of claims 18 to 21, employing a device as claimed in any of claims 1 to 17.

23. The method of claim 22, in which the device is applied to the leg of a patient suffering venous ulcers by said pressure applying means and so that, in use, the device delivers vibrations in the leg of the patient at a frequency of between 20 and 50 Hz, and with an RMS acceleration in the axial direction of the tibial bone of between 5 and 15 ms^{-2}, and in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2}.

24. The method of claim 23, in which the device delivers vibrations in the leg of the patient at a frequency of about 30 Hz, and with an RMS acceleration in the axial direction of the tibial bone of about 10 ms^{-2}, and in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2}.

25. An ulcer or open wound treatment device, substantially as hereinbefore described with reference to the accompanying drawings.

26. A method of treatment of ulcers and wounds of the human or animal body, substantially as hereinbefore described with reference to the accompanying drawings.

ABSTRACT

Leg Ulcer or Wound Vibratory Treatment and Device

An ulcer or open wound treatment device (10) comprises a drive unit (12) adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each orthogonal direction of between 0.1 and 0.5 mm.

A pad (110) is connected to the drive unit, and a strap (~~16~~) enables the pad to be pressed against the limb of the animal or human.

The motor drives an eccentrically mounted weight (~~22~~) to provide oscillations of the casing in a radial plane.

The device is employed to treat a patient suffering from leg ulcers and other wounds by applying three-dimensional vibrations.

[Fig. 1]

Photograph 2. Transducer on Cyclopad

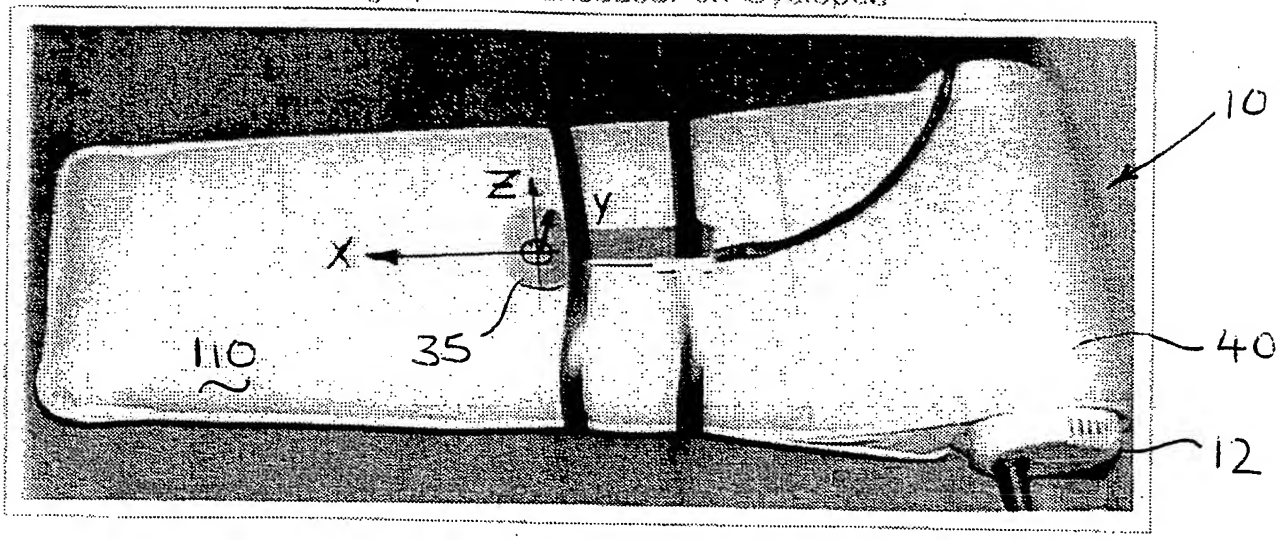


Figure 1

Photograph 4. Basic arrangement, motor at heel, soft support

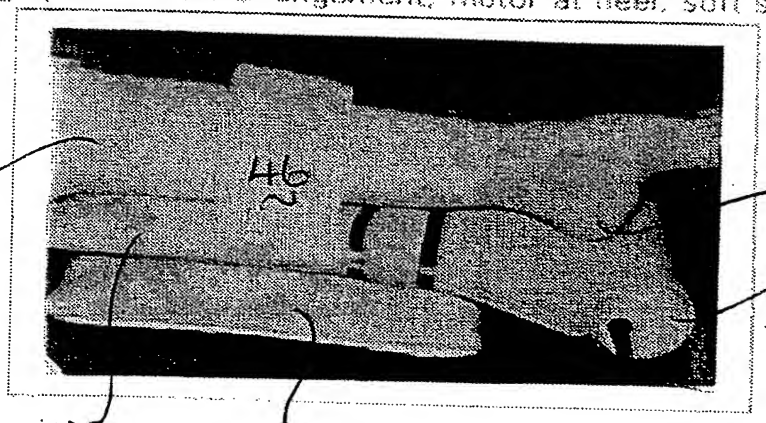


Figure 3

Photograph 5. Alternative arrangement, motor at knee

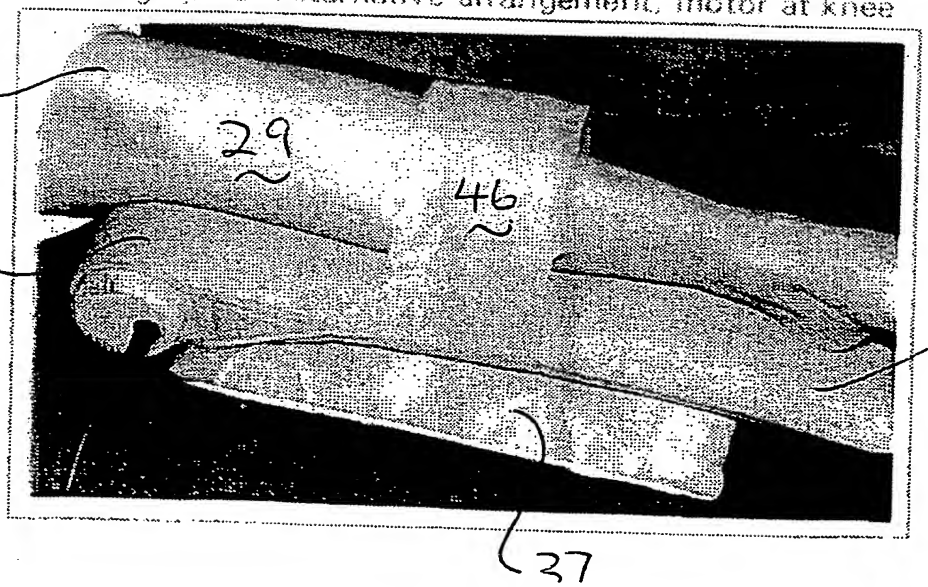
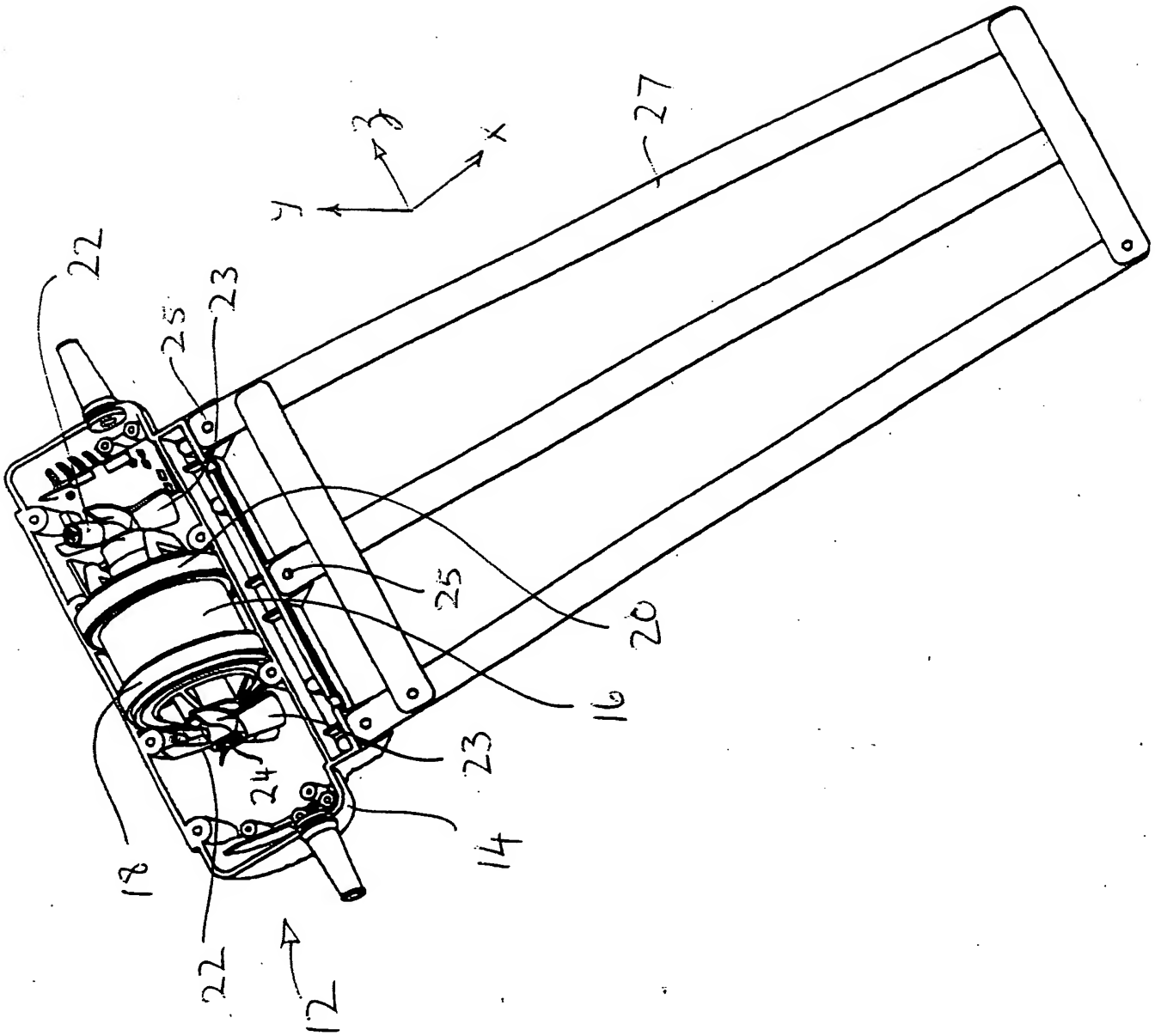


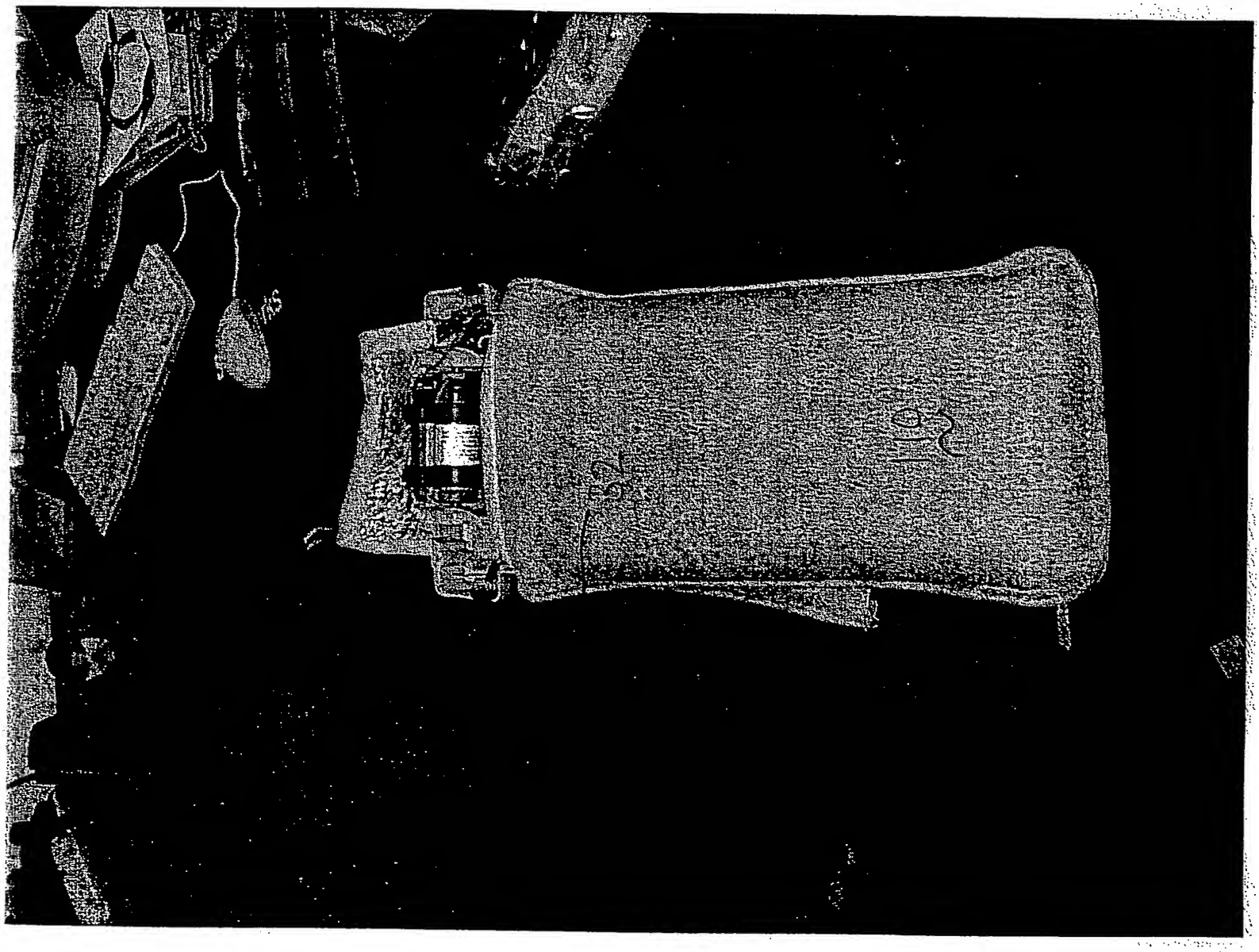
Figure 4

Figure 2



3/13

Figure 5



5

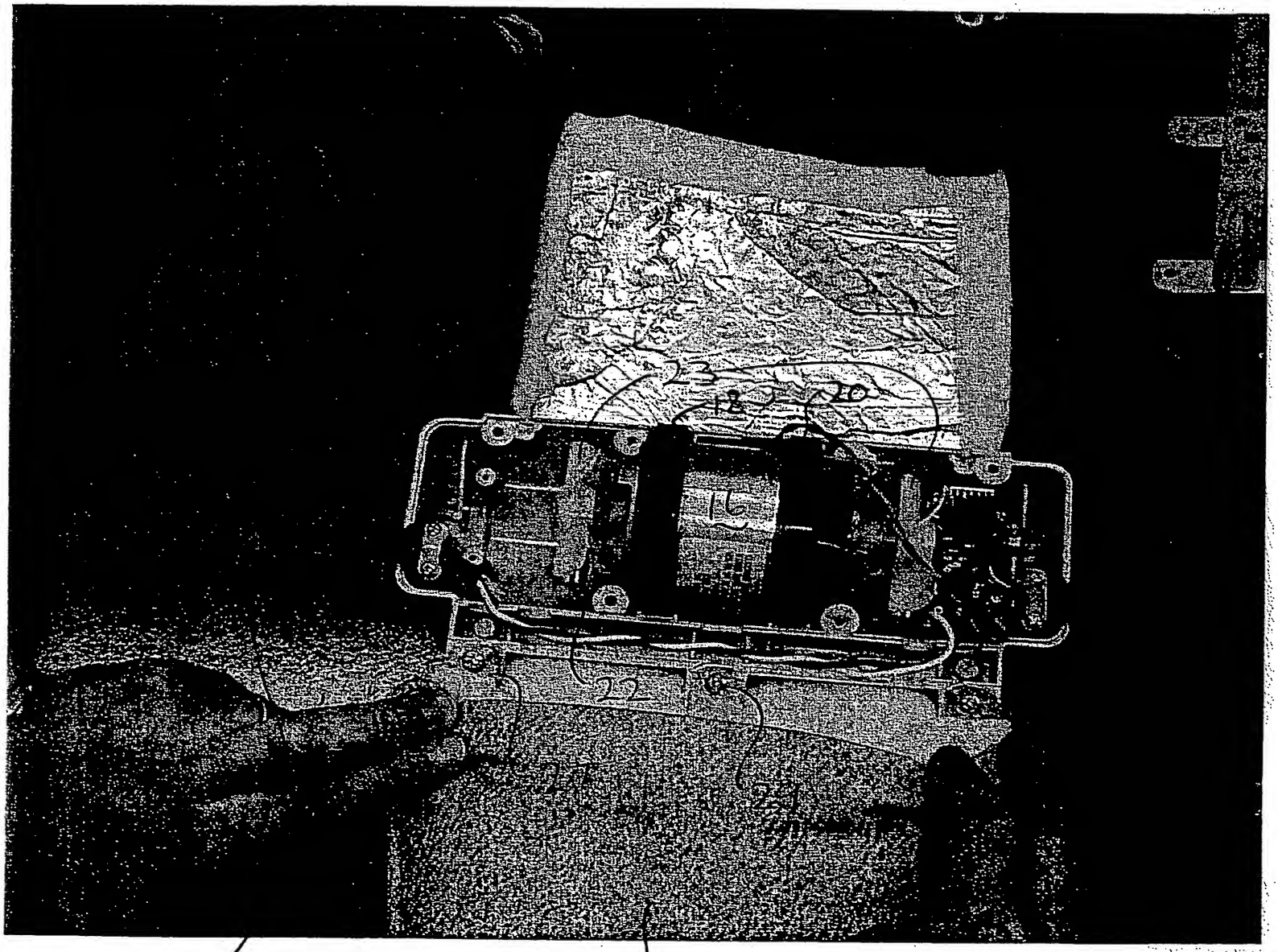


Figure 6

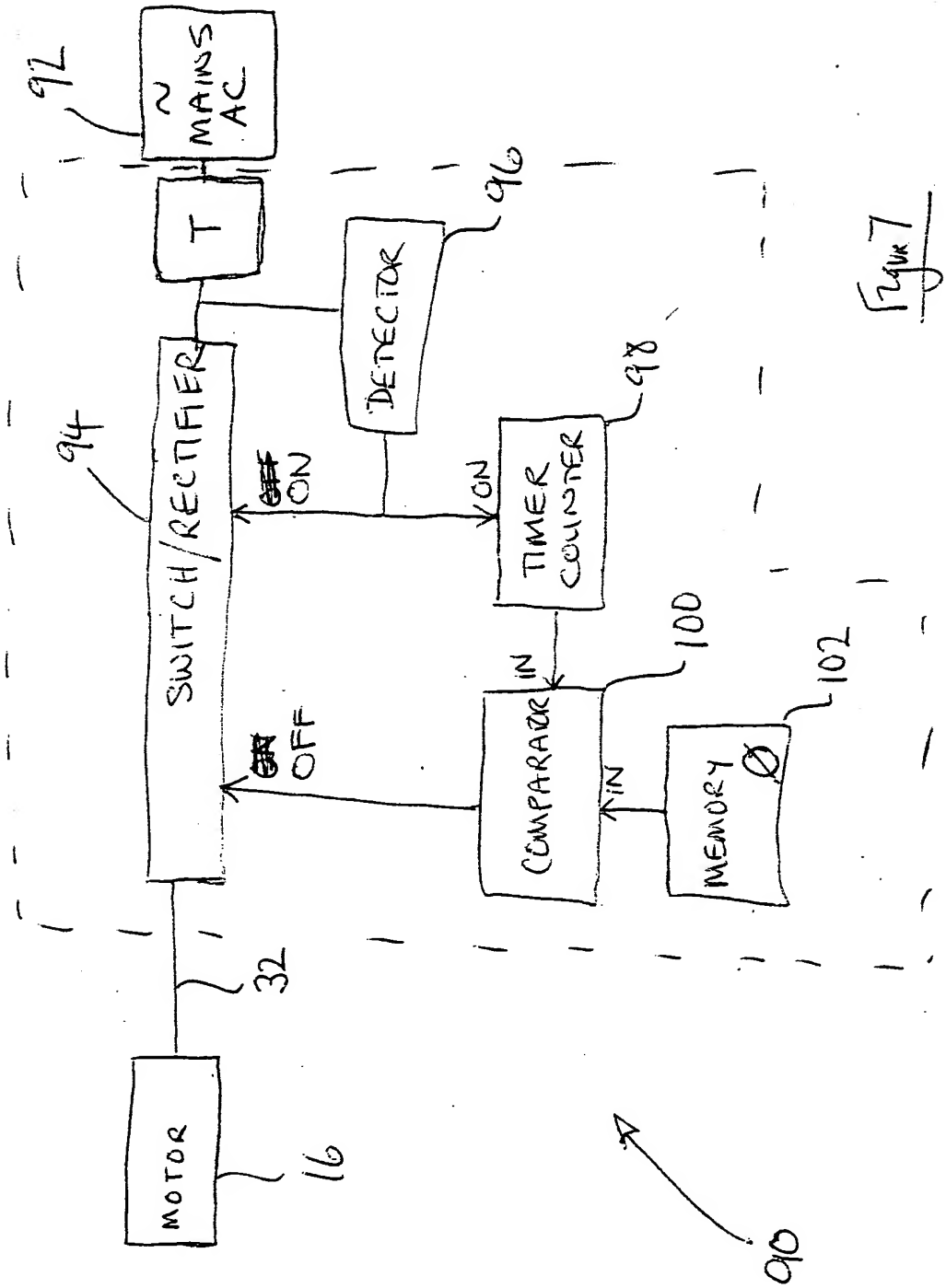

~ MAINS AC
92
T
DETECTOR
96
SWITCH/RECTIFIER
94
ON
OFF
ON
TIMER COUNTER
98
IN
100
COMPARATOR
IN
MEMORY
102
32
MOTOR
16
90

Figure 7

5

2. Cyclodal tests – Magnitude results

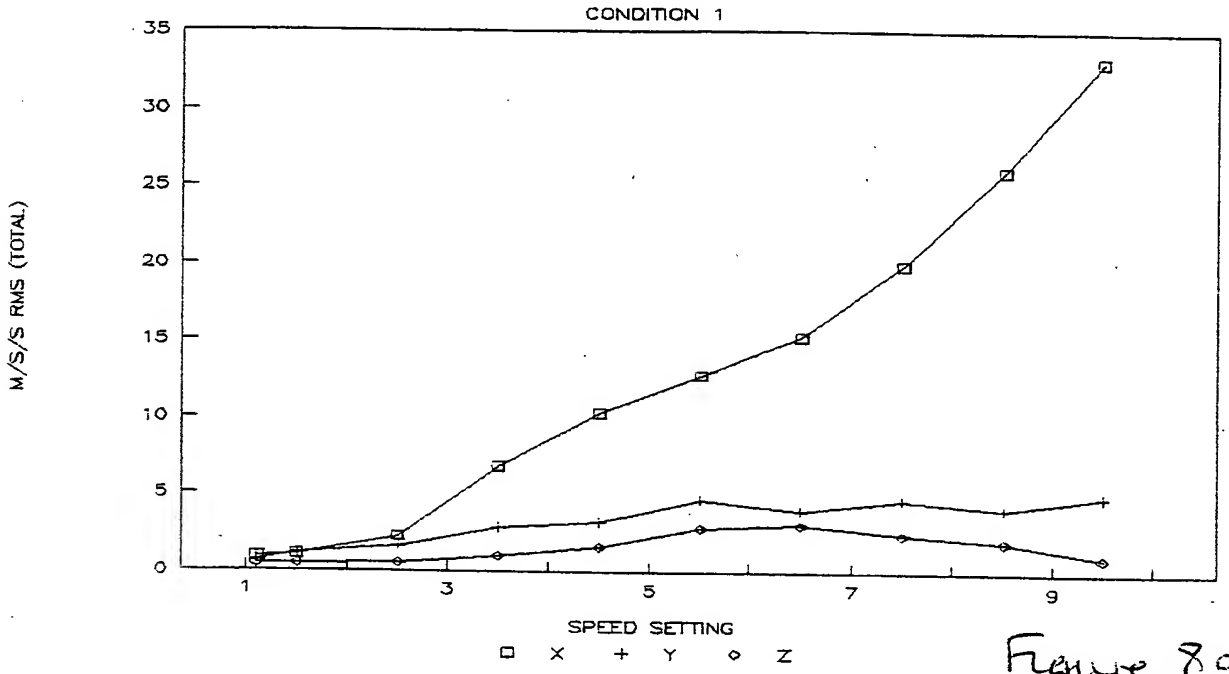


Figure 8a

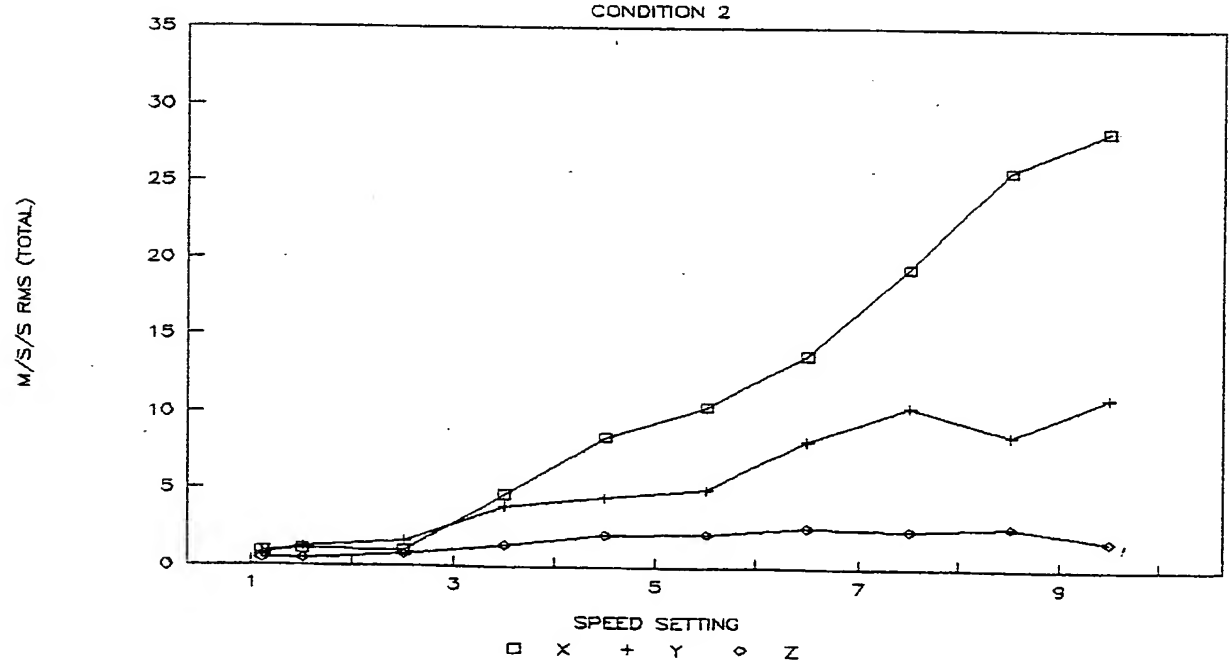


Figure 8b

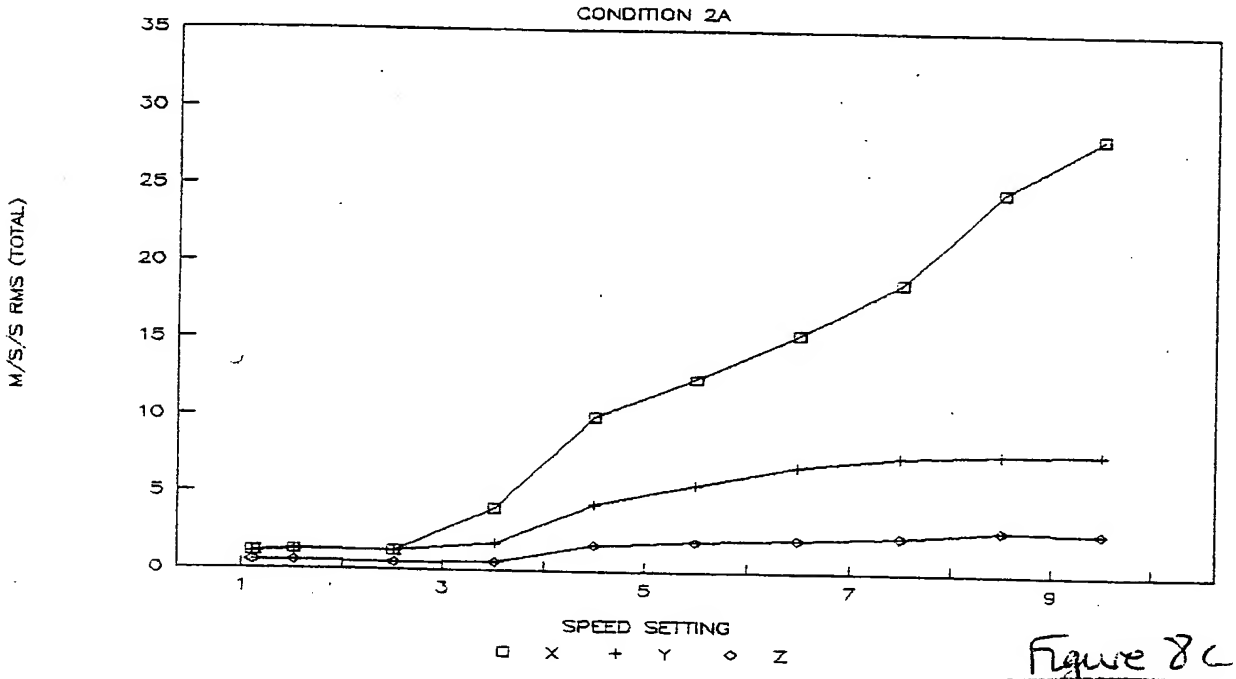


Figure 8c

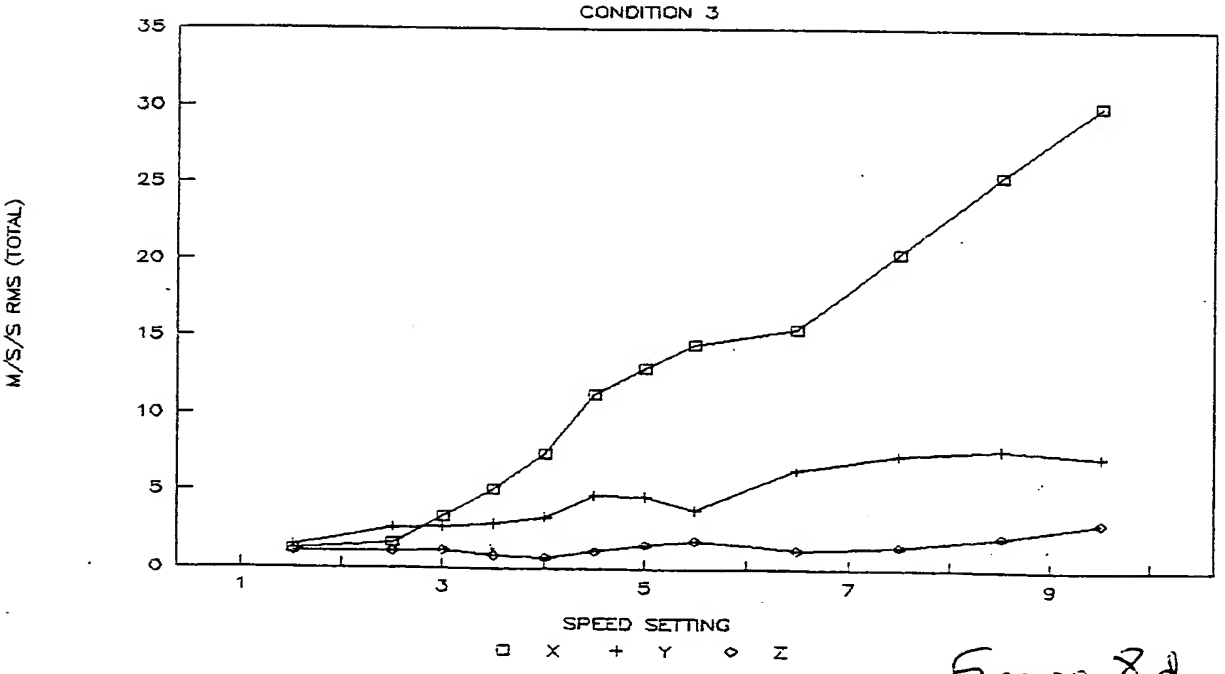


Figure 8d

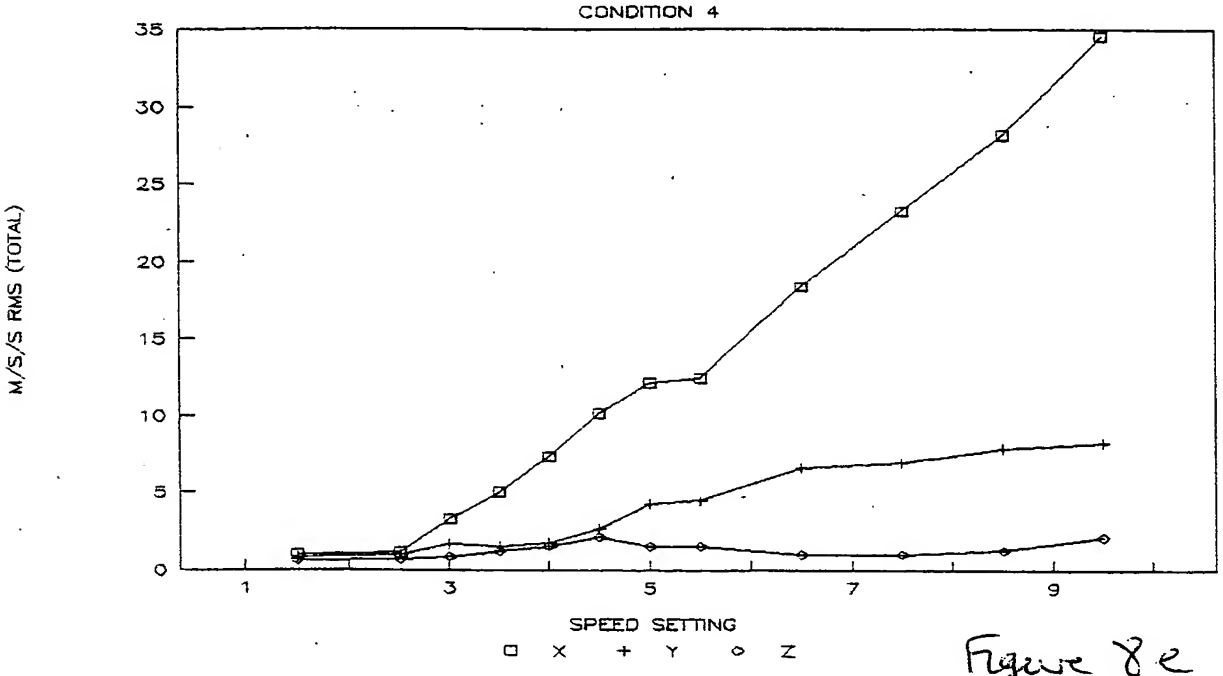


Figure 8e

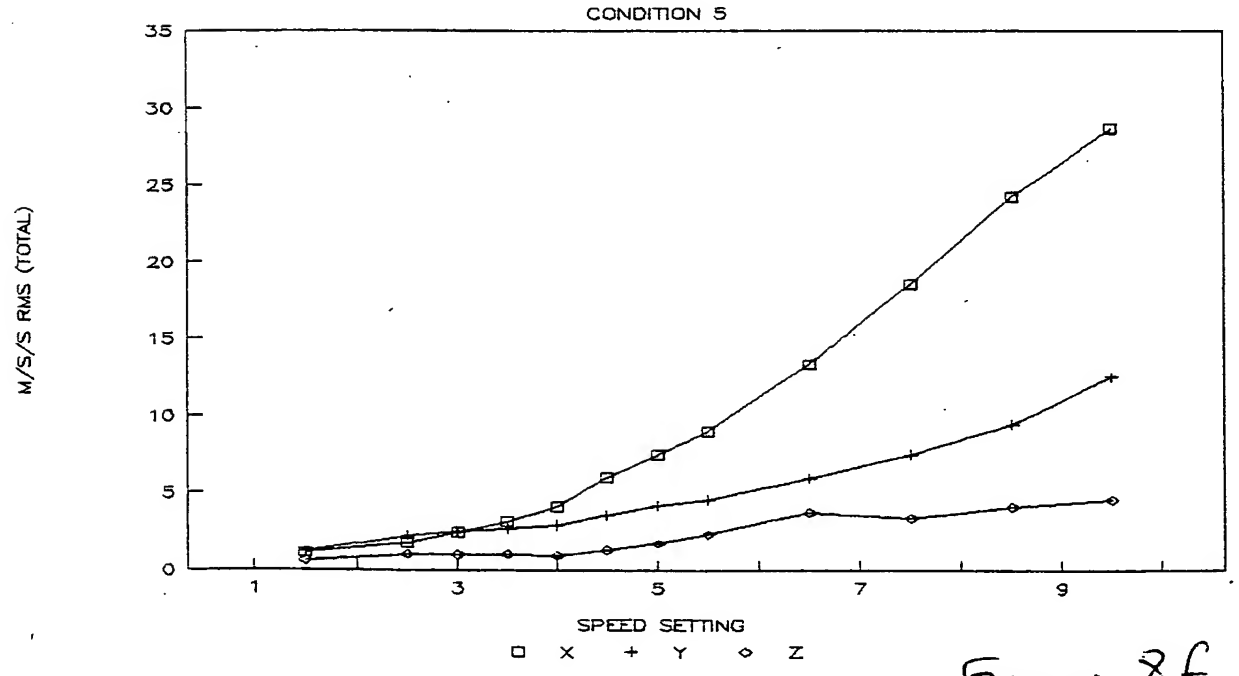


Figure 8f

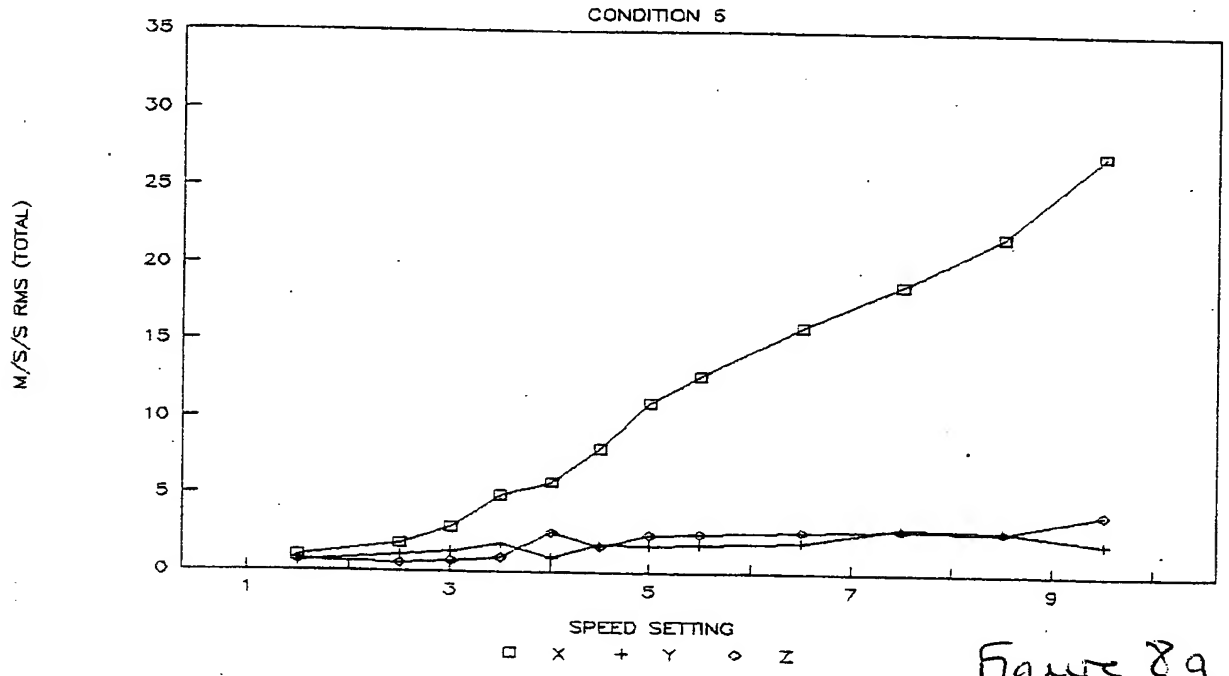


Figure 8g

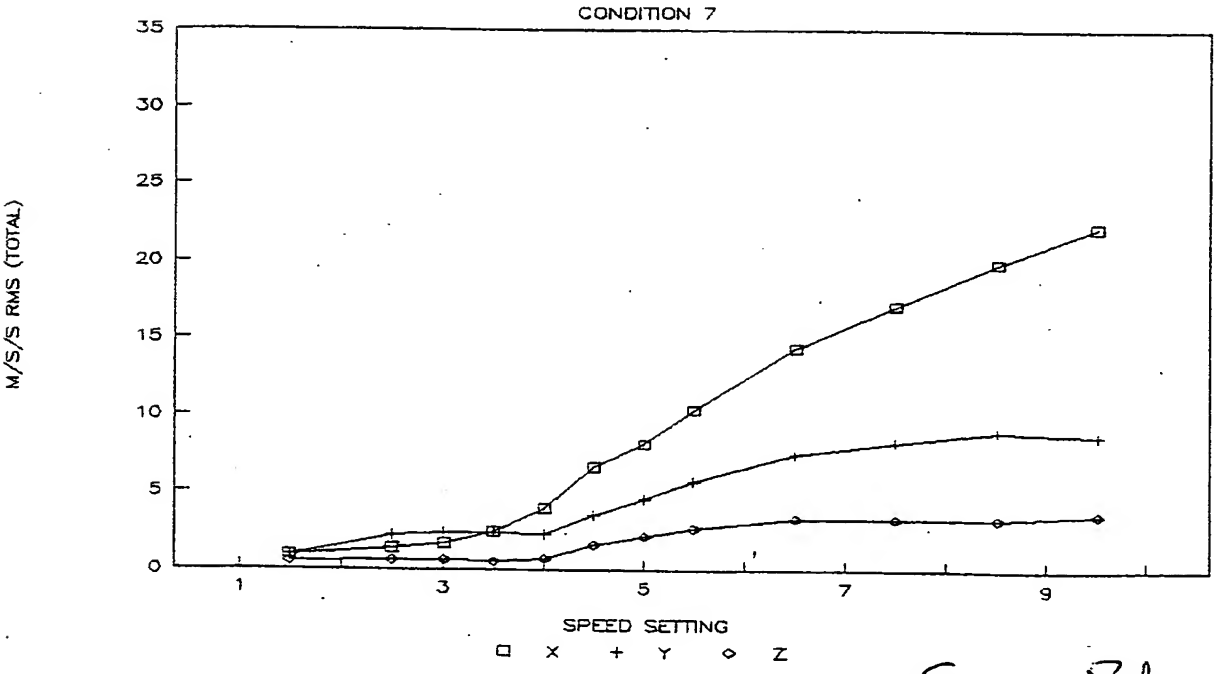


Figure 8h

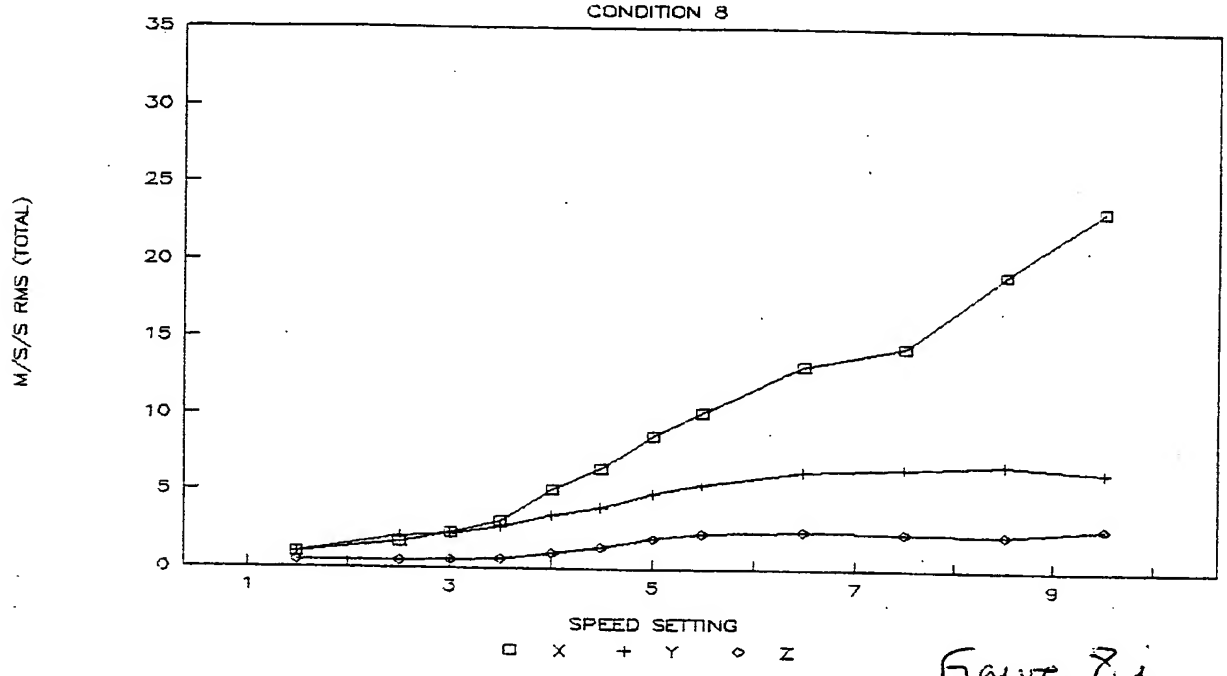


Figure 8.i

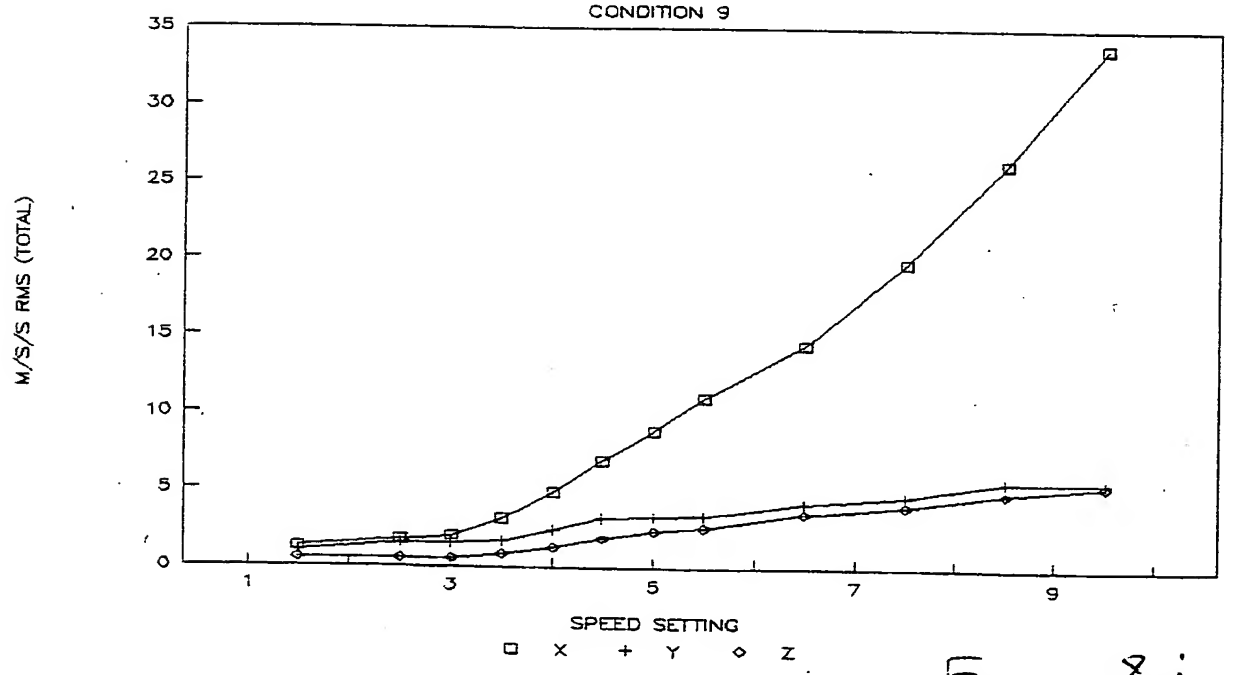


Figure 8.j

4.1. Sample record - setting 4.5

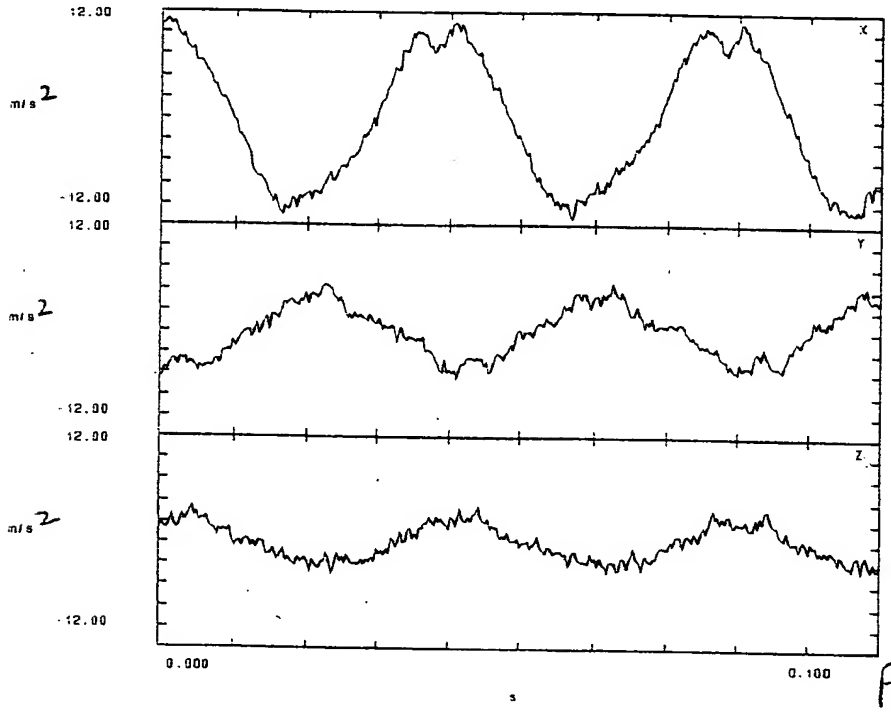


Figure 9a

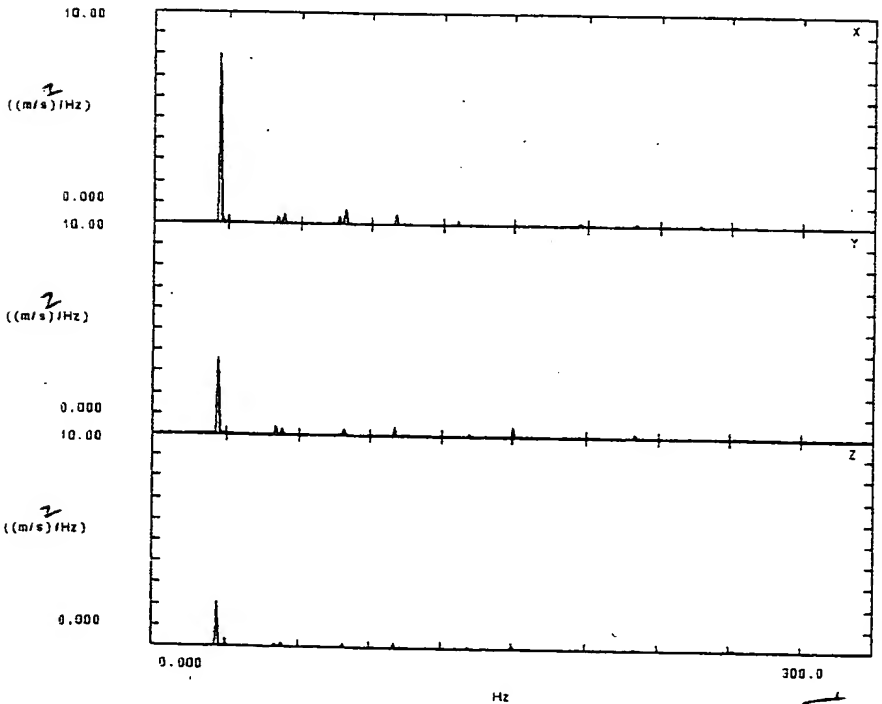


Figure 9b

4.2. Sample record - setting 9.5

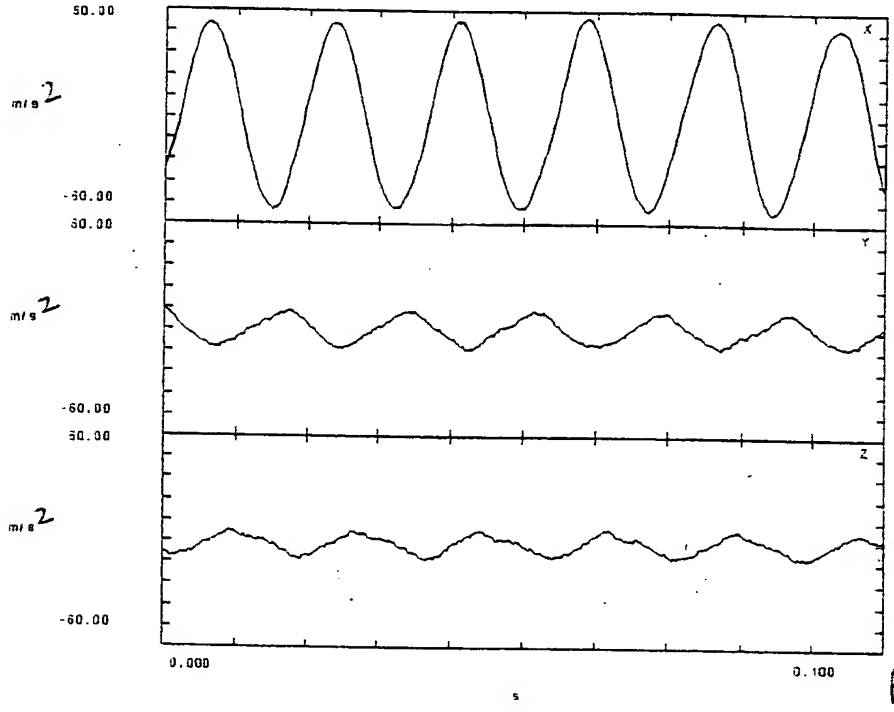


Figure 10a

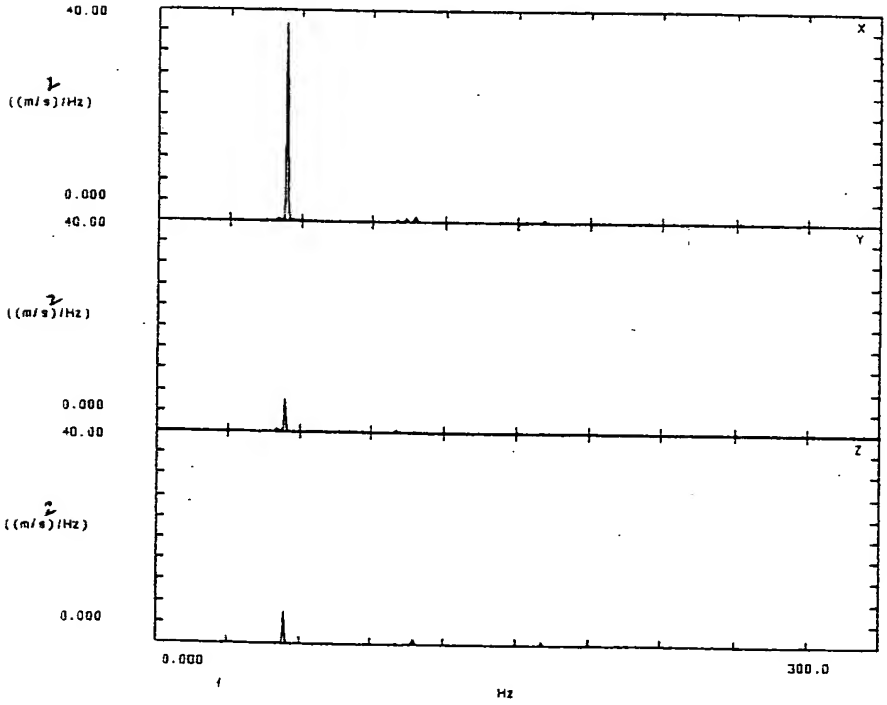


Figure 10b

3. Cycloidal tests - speed/frequency checks

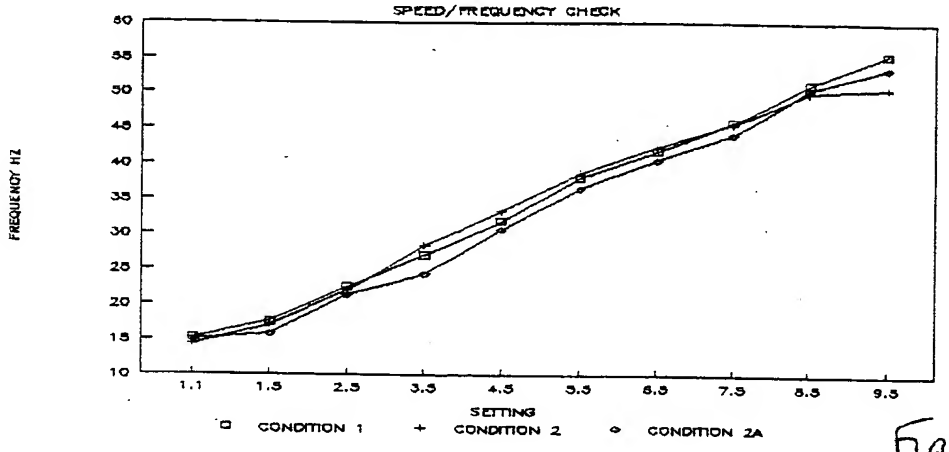


Figure 11a

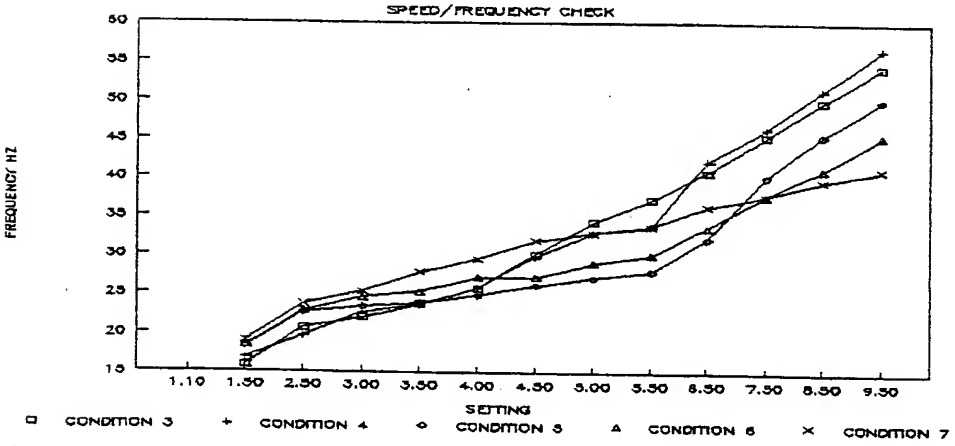


Figure 11b

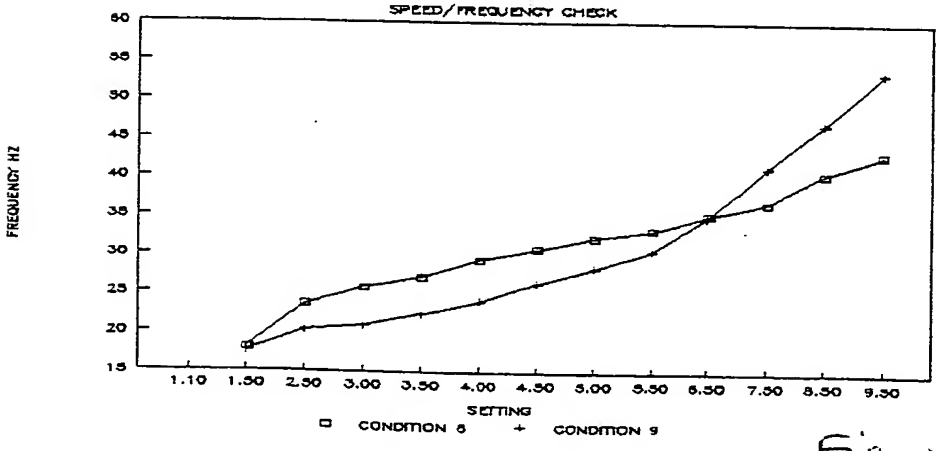


Figure 11c